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EXAMINER	
LOUIE, MANDY C	

ART UNIT	PAPER NUMBER
1792	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/537,391	HIROSHI ET AL.	
	Examiner	Art Unit	
	MANDY C. LOUIE	1792	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16,20 and 21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16,20 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *01/14/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-16, and 20-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

a. Regarding claims 1-3, 12, 16, and 20-21 there appears to be lack of support for the limitation for "repeating a combined step of applying material liquid containing the reagent and then drying the material liquid," whereas the Applicant's original disclosure included a plurality of applying and drying steps in which material liquid containing the reagent is applied and then the material liquid is dried on page 4, lines 18-25, which is not limited to repeating a combined step of applying and drying the liquid material, but rather, a plurality of applying steps and a plurality of drying steps (which can be performed intermittently with a plurality of applying steps) may be provided to form the reagent member.

b. Regarding claims 4, 10-11 and 13, there appears to be lack of support for the limitation for "the material liquid applied to (each of) the reagent layer,"

whereas support is provided for a coating process of the material liquid to reagent holding portions on page 7, lines 5-10.

c. Regarding claim 6, there appears to be lack of support for the limitation "for the reagent layer formed at a bottom of the reagent member," whereas support is provided for forming a reagent with the material liquid by applying to a bottom surface of a reagent holding portion on page 9, lines 19-27.

d. Regarding claim 20, there appears to be lack of support for the limitation "the reagent dots in the group being held in contact with each other."

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 4, 6-7, 10-11 and 13-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Regarding claims 4, 10-11, 13, the limitation "the material liquid applied to (each of) the reagent layers" appears to be indefinite, wherein it is unclear as to how a material liquid is applied to a reagent layer if the material liquid forms the reagent layer and each different reagent layer is separated by a separation layer. For the purpose of examination, "the material liquid applied to the reagent layer" will be interpreted as "the material liquid applied for the reagent layer."

b. Regarding claim 6, the limitation "the reagent layer formed at a bottom of the reagent member" is indefinite, wherein the bottom of the reagent member

may be referred to the opposite surface of the top surface of the reagent member or to the bottom surface of the recess. For the purpose of examination, "the reagent layer formed at a bottom of the reagent member" will be interpreted as "the reagent layer formed at the bottom surface."

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-3, and 10-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Deeg [US 5378638].

Regarding claim 1, Deeg teaches a process for manufacturing an analysis element [title] which comprises a reagent member forming process for providing a base plate (2) with reagent members (A, B, C) [abstract] that includes a stack of at least two reagent layers separated by an intervening separate layer (5) [Fig. 1-3] each of the reagent layers containing a reagent that reacts with a specific component contained in sample liquid and is different from a reagent contained in other reagent layer [abstract],

wherein each of the reagent layer is formed by applying material liquid containing the reagent and then drying the material liquid, and further applying material liquid containing the reagent for a second time [col 4, ln 60-69], where it would have been inherent to the prior art that after applying material liquid for the second time, the material liquid would more or less immediately start drying (repeating a combined step of applying material liquid containing the reagent and then drying the material liquid).

Regarding claim 2, Deeg teaches the combined step of applying and drying the material liquid is performed with use of material liquid containing a same reagent for each of the reagent layer [col 5, ln 13-17].

Regarding claim 3, Deeg teaches the combined step of applying and drying the material liquid can be performed twice [col 4, ln 60-68].

Regarding claim 10, Deeg teaches the material liquid is applied for the reagent layer with use of an inkjet type dispenser [col 8, ln 50].

Regarding claim 11, Deeg teaches the dispenser is designed to dispense a droplet of 20-2000 pL [col 3, ln 29], wherein the dispenser is used for applying the material liquid for the reagent layer in a manner such that a plurality of droplets are attached to an application target portion [col 4, ln 59-64].

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Deeg in view of Maddox [US 5212060].

Teaching of Deeg is aforementioned.

Regarding claim 4, Deeg teaches the material liquid applied for each of the reagent layer contains an amount of reagent in weight per volume [col 9, ln 15]. Although the prior art appears to be silent in teaching the material liquid applied contains 0.1-60 wt% of the reagent, it would have been obvious to one of ordinary skill

in the art to optimize such a workable parameter through routine experimentation, such to provide sufficient amounts of reagent to produce a chemical reaction and lead to rapid detection as taught by Maddox [col 8, ln 56-61], while providing the liquid material at an appropriate viscosity for application (and reduce material cost by controlling the amount of reagent).

5. Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deeg in view of Cottingham [US 5948673].

Teaching of Deeg is aforementioned, but appears to be silent to the base plate comprises a reagent holding portion formed as a recess including a bottom surface and a side surface, wherein the reagent member is formed in contact with the bottom surface. Cottingham remedies this.

Regarding claim 5, Cottingham a device for DNA assay [title], where the device include a base plate comprising a sample material (reagent) holding portion formed as a recess including a bottom surface and side surface wherein the reagent is in contact with the bottom of the surface [Fig. 4].

It would have been obvious to one with ordinary skills in the art at the time of the invention to substitute the base plate of Deeg with the base plate of Cottingham to contain the reagents holding area. One would have been motivated to do so to provide a convenient setup for delivering and confining the liquid sample to react with the reagents, while also increasing the surface area of the reagent members to be place in contact with the liquid sample [Cottingham, col 9, ln 5-9].

Regarding claim 6, Cottingham teaches the reagent located at the bottom surface of the reagent holding portion is placed on the bottom surface with a constant space from the side surface of the holding portion [Fig. 4]. It would have been obvious to one of ordinary skill in the art at the time of the invention to have the reagent be at a constant spaced from the side surface to allow the sample material react with a larger surface area of the reagent to sufficiently react (i.e. dissolve the reagent).

Regarding claim 7, Deeg in view of Cottingham further teaches it would be desirable to adjust the surface area of the sampling area in order to provide sufficient heat to activate the reagent to react with the liquid sample. And since the distance between the side surface and the area applied with the material liquid would influence the surface area of the sampling area with the reagent for heat exposure, it would have been obvious to one of ordinary skill in the art to optimize that distance as a result effective variable through routine experimentation to improve the surface area for heat exposure.

6. Claims 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deeg in view of Cottingham, and further in view of Taguchi et al. [US 5681529].

Teachings of Deeg in view of Cottingham is aforementioned, but appears to be silent in teaching the recess (reagent holding portion) has a depth ranging from 50-200 micrometers (claim 8), where the recess has a volume ranging from 0.05-5 microliters (claim 9). Taguchi et al. teach these deficiencies.

Regarding claims 8 and 9, Taguchi et al. teaches a biological fluid analyzing device [abstract], where sizes of the regions in the analyzing device is described having

a height (depth) of the pathway and chamber regions (recess) of 100 micrometers [column 10, lines 65-67]; where a reagent is applied in sample-treating chamber (2b) to react with the liquid sample [column 6, lines 11-12]. Taguchi et al. also teaches the volume of the sample-treating chamber (2b) is 20 microliters [column 11, lines 11-12]. In addition, Taguchi et al. discloses that there are no restrictions on size shape or material of the analyzing device as one could modify the design for specific test needs [column 5, lines 8-13]. It would have been obvious to one with ordinary skill in the art that the sample-treating chamber (recess) would have a volume of 0.05- 5 microliter by adjusting the width and, or length of the recess to fit the size of any type of reagent member. Moreover, it would have been obvious to one of ordinary skill in the art to optimize the volume or depth of the recess through routine experimentation in order to adjust the amount of sample liquid required to react with the reagent provided therein.

It would have been obvious to one with ordinary skill in the art at the time of the invention to apply Taguchi et al. with the prior art to have a recess that has a depth ranging from 50-200 micrometers and a volume ranging from 0.05-5 microliters. One would have been motivated to do so to manufacture an analyzing device which requires less reagent material to reduce material costs. And while still obtaining a high level of precision in analyzing a liquid sample and be disposable that can be discarded after use [Taguchi, column 3, lines 47-48].

7. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Deeg in view of Demers [US 6117396].

A teaching of Deeg is aforementioned, but appears to be silent in teaching the amount of material liquid applied ranges from 1-200nL. Demers teaches this deficiency.

Regarding claim 12, Demers teaches a device for delivering defined volumes such as reagent [abstract], where the device can deliver a 8 nL or more volume to an analytical piece [column 9, lines 40-41]. It would have been apparent to one with ordinary skill in the art to modify the dispensing device (e.g. nozzle) to deliver a predetermined amount of reagent necessitated by the analytical device for a particular purpose.

It would have been obvious to one with ordinary skill in the art at the time of the invention to apply Demers with the prior art to dispense a range of material liquid from 1-200 nL. One would have been motivated to do so to control the amount of material liquid dispensed to accurately coat the region designated for the reagent member. As well as quickly distributing the material liquid to the appropriate location, while be able to reduce wasting reagent material.

8. Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deeg in view of Hashimoto [US 2003/0083203].

Teaching of Deeg is aforementioned, but appears to be silent in teaching some of the limitations of claims 13-15. Hashimoto remedies this.

Regarding claims 13-15, Hashimoto teaches a method for forming film patterns [title] with inkjet technique [abstract], where after droplets are dispensed onto the substrate, a drying treatment may be performed in order to remove a dispersion medium (solvent) with heat energy. The drying treatment may be with a common hot

plate (holding a heat source with a rear surface of the base plate), or lamp annealing (heat applied by radiant heat from above) [0115].

It would have been obvious to one with ordinary skills in the art at the time of the invention to apply heat energy to dry the reagent layer with reasonable expectation of expediting the drying process of the liquid reagent. Moreover, it would have been obvious to one of ordinary skill in the art to either apply heat from above the reagent or from behind since both techniques would be operable in drying the reagent in a quicker fashion than of air drying.

9. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Deeg in view of Harding [US 2002/0098114].

Teaching of Deeg is aforementioned, but appears to be silent in teaching the limitations of claim 16. Harding remedies this.

Regarding claim 16, Harding teaches microdroplet dispensing for medical diagnostic device [title] with micro-printing [abstract], where average coating thickness of the reagent is about 0.1 micrometer to 1 micrometer [0065]. Furthermore, it would have been obvious to one of ordinary skill in the art to optimize the thickness of the reagent to a desirable final thickness in order to utilize enough reagent material that would react with the liquid sample.

It would have been obvious to one with ordinary skills in the art at the time of the invention to have the reagent have a thickness as suggested by Harding. One would have been motivated to do so to fabricate a relative thin medical device that is light and

convenient, improve reagent thickness uniformity, and decrease the waste of reagent material.

10. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Deeg in view of Cottingham and Dombrowski.

Regarding claim 20, Deeg teaches a process for manufacturing an analysis element [title] which comprises a reagent member forming process for providing a base plate (2) with reagent members (A, B, C) [abstract] where each of the reagent member containing a reagent that reacts with a specific component contained in sample liquid and is different from a reagent contained in other reagent layer [abstract], wherein each of the reagent layer is formed by applying material liquid containing the reagent and then drying the material liquid, and further applying material liquid containing the reagent for a second time [col 4, ln 60-69], where it would have been inherent to the prior art that after applying material liquid for the second time, the material liquid would more or less immediately start drying (repeating a combined step of applying material liquid containing the reagent and then drying the material liquid). Deeg appears to be silent in teaching the base plate comprises a reagent holding portion formed as a recess including a bottom surface and a side surface. Cottingham remedies this.

Regarding claim 20, Cottingham a device for DNA assay [title], where the device include a base plate comprising a sample material (reagent) holding portion formed as a recess including a bottom surface and side surface with the applied reagent spaced at a constant distance from the side surface[Fig. 4].

It would have been obvious to one with ordinary skill in the art at the time of the invention to have a base plate with a recess as a reagent holding portion wherein the reagent is spaced at a constant distance from the side surface of the reagent holding portion. One would have been motivated to do so to effectively confining the liquid sample within an area containing the reagent to allow sufficient reaction while having enough displacement of the liquid sample to substantially react with the reagent by increase surface area for reaction.

Regarding claim 20, Deeg in view of Cottingham teaches the reagent member comprises a group of individual reagent dots which some are held in contact with teach other [Deeg, Fig. 1], the group of reagent dots also includes a plurality of subgroups of reagent dots that contain different reagents [Deeg, abstract].

11. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Deeg in view of Cottingham and Taguchi.

Regarding claim 21, Deeg teaches a process for manufacturing an analysis element [title] which comprises a reagent member forming process for providing a base plate (2) with reagent members (A, B, C) [abstract] where each of the reagent members containing a reagent that reacts with a specific component contained in sample liquid and is different from a reagent contained in other reagent layer [abstract], wherein each of the reagent layer is formed by applying material liquid containing the reagent and then drying the material liquid, and further applying material liquid containing the reagent for a second time [col 4, ln 60-69], where it would have been inherent to the prior art that after applying material liquid for the second time, the material liquid would

more or less immediately start drying (repeating a combined step of applying material liquid containing the reagent and then drying the material liquid). Deeg appears to be silent in teaching the base plate comprises a reagent holding portion formed as a recess including a bottom surface and a side surface. Cottingham remedies this.

Regarding claim 21, Cottingham a device for DNA assay [title], where the device include a base plate comprising a sample material (reagent) holding portion formed as a recess including a bottom surface and side surface [Fig. 4].

It would have been obvious to one with ordinary skill in the art at the time of the invention to have a base plate with a recess as a reagent holding portion. One would have been motivated to do so to effectively confining the liquid sample within an area containing the reagent to allow sufficient reaction. Deeg in view of Cottingham appears to be silent in teaching the base plate comprises a flow path including at least one other reagent member being formed within the flow path other than the recess. Taguchi remedies this.

Regarding claim 21, Taguchi teaches a biological fluid analyzing device [title] with multiple sample treatment chamber [abstract], where 2a chamber may be treated as an interfering substance removing area by applying a reagent to thereto beforehand [col 6, ln 1-8], wherein 2a chamber is within the flow path to another reagent within a different recess (in 2b chamber) for analysis [Fig. 1].

It would have been obvious to one with ordinary skills in the art at the time of the invention to apply a disinfectant reagent within the flow path other than within the recess holding the primary reagent for reaction as suggested by Taguchi. One would have

been motivated to do so to prepare the liquid sample prior to reacting with the primary reagent for more accurate results.

Response to Arguments

3. Applicant's arguments, see page 6, filed 01/14/09, with respect to the rejection(s) of claim(s) 1-16 under 35 USC 103a have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of the prior art aforementioned.

Conclusion

1. No claim is allowed.

2. Claims 1-16, 20-21 are rejected for the reasons aforementioned.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MANDY C. LOUIE whose telephone number is (571)270-5353. The examiner can normally be reached on Monday to Friday, 7:30AM - 5:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy Meeks can be reached on (571)272-1423. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. C. L./
Examiner, Art Unit 1792

/Timothy H Meeks/
Supervisory Patent Examiner, Art Unit 1792